

TWO SITE INFUSION APPARATUS

5 [0001] This application claims priority to U.S. Provisional Application Serial No. 60/451,161, filed February 28, 2003, and is a continuation of U.S. Patent Application Serial No. 10/461,939, filed June 13, 2003, which is a Continuation in Part of U.S. Patent Application Serial No. 10/083,266, filed February 23, 2002, now U.S. Patent No. 6,679,862.

TECHNICAL FIELD

10 [0002] The present invention relates generally to the delivery of a pulsatile fluid pulse, and more particularly, to an apparatus for controllably dividing a pulsatile fluid flow into two or more pulsatile fluid flows.

BACKGROUND OF THE INVENTION

15 [0003] It is sometimes desirable to deliver a fluid using a pulsatile fluid flow or series of pulses. For example, some medication delivery systems which utilize a series of pulsatile fluid pulses to deliver medication, are known in the art. Medication delivery systems may be used to deliver pain control medication and other medications intra-operatively or post-operatively, subcutaneously, and percutaneously to a patient after a surgical, or some other medical, procedure.

20 [0004] For example, United States Patent No. 5,807,075 to Jacobsen et al. discloses a conventional medication delivery system that includes a base housing and a cassette. The base housing of the '075 patent houses electronic components, such as an electric motor, a power source, and an electronic controller, and the cassette of the '075 patent interacts with a supply of the medication to deliver the medication to the patient.

25 [0005] A further example of a conventional medication delivery system is disclosed in United States Patent No. 4,650,469 to Berg et al. This patent discloses a medication delivery system that includes a control module and a reservoir module removably connected to the control module. The control module includes a pump mechanism, valves, a power source, electronic controls, and the like, and the reservoir module
30 includes a container that supplies the medication to be delivered to the patient.

[0006] It is known to use an electric motor in such medication delivery systems, where each revolution or cycle of the motor delivers a preset amount of medication. Such systems are known as positive displacement systems. In such systems, the flow of medication is not pressurized unless it meets a restriction.

5 [0007] Generally, conventional medication delivery systems provide a flow of medication through an output tube which then is delivered to the patient, as required. However in some procedures, medication is required at two locations with respect to the patient, for example, breast augmentation or reconstruction. Another such procedure where medication delivery is desirable at two sites is an autologous graft procedure where
10 it is desirable to deliver medication at both the graft and the donor sites. If the medication provided by the delivery system is pumped through a “Y” connection, then the medication will not be delivered to each site or location evenly for several reasons. First, unequal pressure at the two infusion sites due to elevation or intracompartmental pressure sets up a siphon where flow occurs from the higher pressure side to the lower
15 pressure side in the period between pulses. Furthermore, if the flow of medication on one side of the “Y” has a greater restriction than on the other side, back pressure may reduce or stop the flow of medication on that side. This is undesirable.

[0008] One solution would be to provide a check valve in each leg after the “Y” connection. This solution presents several problems, namely, there is a time delay added
20 by the opening and closing of the check valve and differences in manufacturing tolerances contributing to the delay may also lead to uneven delivery of the medication. Furthermore, most check valves restrict flow when open, and unequal or uncontrollable variations in this restriction would lead to unequal flow.

[0009] Another solution would be to provide a large fluid resistor (small orifice) in each
25 leg. Correctly sizing this orifice would cause the pressure to rise substantially higher than the downstream pressure differences. This pressure could be driven up over several pulses. If the pressure remained higher than the highest downstream pressure, no backflow due to siphoning could occur. Furthermore, the difference in the pressure drop in the two downstream legs could be controlled to remain relatively equal. This solution
30 presents several problems. First, the maximum pressure reached to provide the necessary

flow split accuracy can be very high. This can interfere with other pump features such as an occlusion alarm, and can cause sealing difficulties. Second, if the pump has a user selectable flow rate, the size of the glass orifice must be fixed to work with the lowest possible flow rate. This aggravates the maximum pressure problem should the pump be
5 used at its highest flow rates.

[0010] The present invention is aimed at one or more of the problems set forth above.

SUMMARY OF THE INVENTION AND ADVANTAGES

[0011] In one aspect of the present invention, an apparatus for use in delivering pain
10 medication to separate locations from a single source of pressurized medication is provided. The apparatus includes a valve housing, a cap, and a flexible diaphragm. The valve housing includes a first end and a second end and an inlet passage. The first end includes first and second outlet orifices. The cap has a closed end and an open end and is removably coupled to the valve housing at the open end. The flexible diaphragm is
15 coupled between the cap and the valve housing and is movable from a closed position to an open position. The flexible diaphragm seals a pressure chamber from the first and second outlet orifices when in the closed position and opens the first and second outlet orifices to the pressure chamber when in the open position.

[0012] In another aspect of the present invention, an apparatus for use in delivering pain
20 medication to separate locations from a single pulsatile flow of medication, is provided. The apparatus includes a valve housing having a first end and a second end. The first end includes first and second outlet orifices. The second end forms a pressure chamber. The valve housing further includes an inlet orifice coupled to the pressure chamber by an inlet passage. The first and second outlet orifices are coupled to the pressure chamber by first
25 and second outlet passages, respectively. A cap has a closed end and an open end and is removably coupled to the valve housing at the open end. A flexible diaphragm is coupled between the cap and the valve housing and is movable from a closed position to an open position, the flexible diaphragm sealing the pressure chamber from the first and second outlet orifices when in the closed position and opening the first and second outlet orifices

to the pressure chamber when in the open position. The second end of the valve housing and the flexible diaphragm form a pressure chamber. The valve housing further includes an inlet orifice coupled to the pressure chamber by an inlet passage. The first and second outlet orifices are coupled to the pressure chamber by first and second outlet passages,
5 respectively.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

10 [0014] Figure 1 is a first isometric view of a two site infusion apparatus, according to an embodiment of the present invention;

[0015] Figure 2 is a second isometric view of the two site infusion apparatus of Figure 1;

[0016] Figure 3 is a top down view of the two site infusion apparatus of Figure 1;

15 [0017] Figure 4 is a side view of the two site infusion apparatus of Figure 1;

[0018] Figure 5 is a bottom view of the two site infusion apparatus of Figure 1;

[0019] Figure 6 is a first cut-away view of the two site infusion apparatus of Figure 1;

[0020] Figure 7 is a second cut-away view of the two site infusion apparatus of Figure 1;

20 [0021] Figure 8 is a graph illustrating operating parameters of the present invention;

[0022] Figure 9 is a first isometric view of a two site infusion apparatus, according to a second embodiment of the present invention;

[0023] Figure 10 is a second isometric view of the two site infusion apparatus of Figure 9;

25 [0024] Figure 11 is a top down view of the two site infusion apparatus of Figure 9;

[0025] Figure 12 is a side view of the two site infusion apparatus of Figure 9;

[0026] Figure 13 is a bottom view of the two site infusion apparatus of Figure 9;

[0027] Figure 14 is a first cut-away view of the two site infusion apparatus of Figure 9;

[0028] Figure 15 is a second cut-away view of the two site infusion apparatus of Figure

30 9;

[0029] Figure 16 is a diagrammatical illustration of a tube set including the two site infusion apparatus of Figure 9; and,

[0030] Figure 17 is a second diagrammatical illustration of the tube set of Figure 16.

DETAILED DESCRIPTION OF THE INVENTION

5 [0031] With reference to the drawings and in operation, the present invention provides an apparatus **10** for use in delivering pain medication to separate locations from a single pulsatile source of medication (or two site infusion apparatus). In one embodiment, the source of medication is a medication delivery system which includes a positive displacement pump (not shown). For example, the medication delivery system could
10 include an electrical motor. The system is designed to deliver through a tube or inlet tube **12** a preset amount of medication every revolution or cycle of the motor. The rate at which medication is delivered may be set by varying the time between cycles of the motor.

[0032] In one aspect of the present invention, the two site infusion apparatus **10** is
15 coupled to the output tube **12**. The two site infusion apparatus **10**, as discussed below, splits the medication delivered from the delivery system and delivers the medicine through first and second outlet orifices **14A**, **14B**.

[0033] The apparatus **10** includes a valve housing **16**. The valve housing **16** includes a first end **18** and a second end **20**. The first end **18** includes the first and second outlet
20 orifices **14A**, **14B**.

[0034] An end cap **30** has a closed end **32** and an open end **34**. The end cap **30** is removably coupled to the valve housing **16** at the open end **34**. A flexible diaphragm **36** is coupled between the end cap **30** and the valve housing **16** and is movable from a closed position to and an open position by the fluid energy of the pulse. The second end **20** of
25 the valve housing **16** and the flexible diaphragm **36** form a pressure chamber **22**. The valve housing **16** further includes an inlet orifice **24**. The inlet orifice **24** is coupled to the pressure chamber **22** by an inlet passage **26**. The first and second outlet orifices **14A**, **14B** are coupled to the pressure chamber **22** by first and second outlet passages **28A**, **28B**, respectively. The flexible diaphragm **36** seals the pressure chamber **22** from the first
30 and second outlet orifices **28A**, **28B** when the flexible diaphragm **36** is in the closed

position and opens the first and second outlet orifices **28A**, **28B** to the pressure chamber **22** when the flexible diaphragm **36** is in the open position.

[0035] The valve housing **16** also includes a routing passageway **38** adjacent the inlet passage **26**. The routing passageway **38** allows the medication delivery system inlet tube **12** to be secured within the valve housing **16**. In one embodiment of the present invention, the end of the inlet tube **12** coated with a solvent and inserted through the inlet passage to the inlet orifice **24**. The inlet orifice **24** and the output tube **12** have an interference fit. The solvent bonds the inlet tube **12** and the inlet orifice **24**.

[0036] As shown, in one embodiment of the present invention, the open end **34** of the cap **30** has an outer perimeter **38**. The outer perimeter **38** includes a ridge **40**. The second end **20** of the valve housing **16** includes a detent **42** along its outer perimeter **44**. The detent **42** receives the ridge **40** which allows the valve housing **16** and the end cap **30** to be removably snapped together.

[0037] In another aspect of the present invention, the apparatus **10** includes a biasing mechanism **44** coupled between the cap **30** and the flexible diaphragm **36** for biasing the flexible diaphragm **36** towards the closed position. In one embodiment of the present invention, the biasing mechanism **44** includes a biasing spring **46**. The biasing spring **46** may be either tubular or conical.

[0038] In another aspect of the present invention, a piston **48** may be juxtaposed between the biasing spring **46** and the flexible diaphragm **36**. In one embodiment, the flexible diaphragm **36** includes a piston receiving aperture **50** for receiving a first end **52** of the piston **48**.

[0039] As shown, in one embodiment, the piston **48** is hollow and includes a spring receiving chamber **54**. The end cap **30** includes a spring positioning pin **56**. One end of the spring **46** is seated within the spring receiving chamber **54** and the other end is centered on the spring position pin **56**.

[0040] In another aspect of the present invention, the apparatus **10** includes first and second bushings **58A**, **58B** which are located within and have an interference fit with the first and second outlet orifices **14A**, **14B**. First and second flow restricting components **60A**, **60B** are positioned within and have an interference fit with the first and second

bushings **58A**, **58B**, respectively. Flexible outlet tubes (not shown) are coupled to the flow restricting components **60A**, **60B** to deliver medication to the sites, as needed.

[0041] In one aspect of the present invention, the inner diameter of the flow restricting components **60A**, **60B** are relatively small, e.g., 0.001 to 0.002 inches and a small manufacturing tolerance. The flow restricting components **60A**, **60B** are dimensioned to provide a large resistance to the flow of medication relative to resistance provided by the flexible outlet tubes and the sites where the medication is delivered. This assists in controlling the back pressure and thus minimizing the risk of uneven back pressure causing an unequal amount of medication to be delivered to the two sites.

[0042] In another aspect of the present invention, the flexible diaphragm **36** includes an integrally molded O-ring **62** around its outer perimeter **64**. The O-ring **62** is press fit within a circular groove **66** in the valve housing **16**. The valve housing **16** includes one or more air release apertures **68** which allow air to escape the groove **66** as the O-ring **62** is pressed into the groove **66**. The O-ring **62** and the groove **66** ensures that the outer perimeter **64** is coupled to the valve housing, thereby forming the pressure chamber **22**.

[0043] In operation, the medication delivery system delivers medication through the inlet tube **12** in pulses. With reference to Figure 8, when the flexible diaphragm **36** is in the closed position, the flexible diaphragm **36** creates a seal on the outlet valve seats. As fluid is pumped in, a pressure is created (P_{inlet}) within the pressure chamber **22**. With the flexible diaphragm **36** in the closed position, no flow of medication is allowed from the pressure chamber **22** to the output orifice **14A**, **14B**. Thus, while the flexible diaphragm **36** is in the closed position, the pressure at the outlet orifices **14A**, **14B** (P_{outlet}) is substantially zero.

[0044] When the “pulse” of medication from the medication delivery system begins, P_{inlet} , quickly ramps up from a non-zero value. When the force exerted by the pressurized medication within the pressure chamber **22** on the flexible diaphragm **36** is great enough to overcome the force exerted by the biasing mechanism **44** (P_T), the flexible diaphragm **36** is moved from the closed position towards the open position (t_1). After the flexible diaphragm **36** is moved away from the closed position, fluid flows out of the valve and ramps down towards a non-zero value until the force exerted by the biasing mechanism

44 overcomes the force exerted on the flexible diaphragm by the medication within the pressure chamber 22 (t_2). The rate of fluid flow and therefore pressure decrease is controlled by the flow restricting components 60A, 60B. This control is important since too low of a restriction would not force a complete opening of the valve. In that case the restriction of flow across the valve seats would be significant and minor variations in manufacturing tolerances and/or finishes would control the flow resistance and resultant distribution. With proper flow restrictor selection, the apparatus 10 fully opens and this does not occur.

[0045] Likewise, when the flexible diaphragm 36 is moved away from the closed position, P_{outlet} quickly ramps up to a pressure substantially equal to or slightly less than P_{inlet} . While the flexible diaphragm 36 is open, P_{inlet} tracks P_{outlet} . Since the resistance seen at the first and second orifices 14A, 14B is a result of the resistance of the first and second flow restricting components 60A, 60B, P_{outlet} at the first and second orifices 14A, 14B are substantially equal. Once the flexible diaphragm 36 closes, P_{outlet} quickly drops back down to substantially zero.

$$V_T = \int_{T_D}^{T_F} \dot{V}_T dt$$

$$\text{Since } \dot{V} = \dot{V}_A + \dot{V}_B, \text{ and } V_T = V_A + V_B$$

20 then,

$$V_A = \int_{T_D}^{T_F} \dot{V}_A dt$$

$$V_B = \int_{T_D}^{T_F} \dot{V}_B dt$$

$$\text{But we know that } \dot{V} = \frac{\Delta P}{R_T} = \frac{P_{outlet} - P_B}{R_T}$$

$$25 \therefore V_A = \int_{T_D}^{T_F} \frac{P_{outlet} - P_{DA}}{R_A + R_{DA}} dt$$

and

$$V_B = \int_{T_D}^{T_F} \frac{P_{outlet} - P_{DB}}{R_B + R_{DB}} dt$$

Thus, if $P_{outlet} \gg |P_{DA} - P_{DB}|$

and $R \gg R_D$

and $R_A \approx R_B$

5 then,

$V_A \approx V_B$ (Approximately Equal Flow)

[0046] With reference to Figures 9-15, a two site infusion apparatus 110 according to another embodiment of the invention is shown. In Figures 9-15, similar parts are labeled the same as in the previous Figures.

10 [0047] In the second embodiment, an end cap 130, with a generally cylindrical shape, has a closed end 132 and an open end 134. The end cap 130 is removably coupled to the valve housing 16 at the open end 134. For example, the end cap 130 may be bonded to the valve housing 16 by an adhesive. In one aspect of the invention, gaps in the adhesive bonding the end cap 130 to the valve housing 16 allow air to escape. The flexible
15 diaphragm 36 is coupled between the end cap 130 and the valve housing 16 and is movable from a closed position to an open position, as described above.

[0048] As shown, the open end 134 of the cap 130 has an outer perimeter 138. The outer perimeter 138 includes an internal flange 140 which mates with the detent 42 on the valve housing 16 which allows the valve housing 16 and the end cap 130 to be removably
20 snapped together.

[0049] The apparatus 110 includes a biasing mechanism 144 coupled between the cap 130 and the flexible diaphragm 36 for biasing the flexible diaphragm 36 towards the closed position. In one embodiment of the present invention, the biasing mechanism 144 includes a biasing spring 146 with a generally conical shape.

25 [0050] A piston 148 is juxtaposed between the biasing spring 146 and the flexible diaphragm 136. The piston receiving aperture 50 receives a first end 152 of the piston 148.

[0051] The piston 148 is hollow and includes a spring receiving chamber 154. The end cap 130 includes a spring positioning member 156. One end of the spring 146 is seated

against seatings **158** within the spring receiving chamber **154** and the other end is centered on the spring positioning member **156**.

[0052] With reference to Figures 16-18, an exemplary tube set **68** including the two site infusion apparatus **110** of the second embodiment is shown. The tube set **68** may be used with a delivery system (not shown). A suitable delivery system is disclosed in U.S. Patent Application Serial No. 10/461,939, filed June 13, 2003, which is hereby incorporated by reference.

[0053] The infusion tube set **68** includes a first connector **70** for connection to the delivery system, an on/off clamp **72** and an inline filter **74**. Tubing **76** couples the connector **70** with the inline filter **74** and the inline filter **74** with the two site infusion apparatus **110**. Tubing **76** also connects the first and second flow restricting components **60A**, **60B** to second and third connectors **78A**, **78B**.

[0054] Other aspects and features of the present invention can be obtained from a study of the drawings, the disclosure, and the appended claims.

<u>ELEMENT LIST</u>		
	10	two site infusion apparatus
	12	medication delivery system
		output tube or inlet tube
5	14A	first outlet orifice
	14B	second outlet orifice
	16	valve housing
	18	first end of valve housing
	20	second end of valve housing
10	22	pressure chamber
	24	inlet orifice
	26	inlet passage
	28A	first outlet passage
	28B	second outlet passage
15	30	end cap
	32	closed end
	34	open end
	36	flexible diaphragm
	38	outer perimeter
20	40	ridge
	42	detent
	44	biasing mechanism
	46	biasing spring
	48	piston
25	50	piston receiving aperture
	52	first end of the piston
	54	spring receiving chamber
	56	spring positioning pin
	58A	first bushing
30	58B	second bushing
	60A	first glass tube
	60B	second flow restriction
		components
	62	integral O-ring
35	64	outer perimeter of flexible
		diaphragm
	66	groove
	68	tube set
	70	first connector
40	72	on/off clamp
	74	inline filter
	76	tubing
	78A	second connector
	78B	third connector
45	110	two site infusion apparatus
	130	end cap
	132	closed end
	134	open end
	138	outer perimeter
50	140	internal flange
	154	spring receiving chamber
	156	spring positioning member
	158	seatings